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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,870	06/05/2000	Stephen C. Goshorn	690022.547	1301

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1642

DATE MAILED: 01/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/589,870	GOSHORN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Stephen L. Rawlings, Ph.D.	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 October 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 18-22,24-39 and 65 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 18-22,24-39 and 65 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Continued Examination Under 37 CFR § 1.114***

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicants' submission filed on October 18, 2002 (Paper No. 18) has been entered.
2. The amendment filed October 18, 2002 in Paper No. 19 is acknowledged and has been entered. Claim 23 has been canceled. Claims 18, 24-26, and 65 have been amended.
3. Claims 18-22, 24-39, and 65 are pending in the application and are currently under prosecution.

### ***Grounds of Claim Rejections Withdrawn***

4. Unless specifically reiterated below, the grounds of claim rejections set forth in the previous Office action mailed May 21, 2002 (Paper No. 16) have been withdrawn.

Regarding the grounds of claim rejection under 35 USC § 112, second paragraph for the reasons set forth in the previous Office actions, Applicants' amendment and remarks have served to clarify that in claim 24, the terms "first polypeptide" and "second polypeptide" are merely meant to distinguish one polypeptide from the other, and are not meant to indicate the amino-terminal polypeptide and the carboxyl-terminal peptide, respectively.

### ***Grounds of Claim Rejections Maintained and Relied to Applicants' Remarks***

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 18-22, 24-39, and 65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using the single-chain antibody-streptavidin fusion proteins huNR-LU-10 scFvSA and B9E9 scFvSA, does not reasonably provide enablement for making or using any other claimed fusion protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons set forth in the Office Action mailed June 22, 2001 (Paper No. 8).

Applicants have traversed these grounds of rejection under 35 USC § 112, first paragraph. Applicants have asserted that the specification provides an enabling disclosure because the specification discloses well-known methodology for testing the ability of a fusion protein to bind biotin and maintain solubility in the periplasmic space.

Applicants' arguments have been carefully considered, but have not been found persuasive. Although the methodology necessary to determine whether a particular species of the claimed genus of streptavidin fusion proteins might be known in the art, the amount of guidance, direction, and exemplification set forth in the specification would not be sufficient to enable the skilled artisan to have a reasonable expectation of successfully making and using at least a substantial number of the members of the claimed genus of fusion proteins without having the need to perform additional, undue experimentation. The reasons have been set forth in the previous Office actions, but the factors that have been considered in determining whether undue experimentation would be required are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). These factors include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or

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unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The references cited as support of the Office's position provide an indication of the state of the art and the level of unpredictability associated with the art. *In re Fisher*, 1666 USPQ 19 24 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions could result in substantially different biological and pharmacological activities. The instant claims encompass a genus of fusion proteins comprising portions of streptavidin or functional variants thereof having amino acid sequences that are at least 90% identical to the amino acid sequence set forth in SEQ ID NO: 2 and retain the ability to bind biotin, but the specification does not teach one to make at least a substantial number of members of the claimed genus. Because of the unpredictable nature of the art, in the absence of a necessary and sufficient amount of guidance and direction, and exemplification, one skilled in the art could not reasonably expect to successfully make or use at least a substantial number of the members of the claimed genus without the need to perform additional, undue experimentation.

Additionally, in *Colbert v. Lofdahl*, 21 USPQ2d, 1068, 1071 (BPAI 1992) the court has decided:

It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

By the same token, it is not sufficient to define the instantly claimed invention as comprising a first polypeptide that retains the ability to bind biotin, and expect the practitioner to discover how to make the claimed invention, and moreover to determine which species of the claimed genus of fusion polypeptides can be made and used in accordance with the teachings of the specification. Moreover, although Applicants have argued that the disclosure is reasonably enabling because the specification discloses well known methods that the skilled artisan could use to determine which fusion proteins

comprising variants of SEQ ID NO: 2 are able to bind biotin, as the specification does not teach how at least a substantial number of the claimed fusion proteins comprising an amino acid sequence that is less than 100% identical to SEQ ID NO: 2 and which bind biotin can be made, the artisan would be left to manufacture each and every species of the claimed genus of fusion proteins having an amino acid sequence varying from the amino acid sequence set forth in SEQ ID NO: 2 by at most 10% and then determine whether the protein retains the ability to bind biotin. Because one would reasonably imagine that the claims encompass many non-working embodiments, which could not be identified by any means other than producing a particular species of the claimed genus of fusion proteins comprising an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO: 2 and determining whether or not the species binds biotin, finding the working embodiments among the possibilities would require undue experimentation.

Finally, due to the complexities of engineering antibodies, as discussed primarily in the first Office action, the skilled artisan could not have a reasonable expectation of success in making and using at least a substantial number of members of the claimed genus of fusion proteins without needing to perform additional, undue experimentation.

#### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 18-39 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubel, et al (*Journal of Immunological Methods* 178: 201-209, 1995; Form PTO-1449, Paper No. 6, page 3), as evidenced by Kipriyanov, et al (*Human Antibodies and Hybridomas* 6: 93-101, 1995; Form PTO-1449, Paper No. 6, page 4), in view of Desplancq, et al (*Protein Engineering* 7: 1027-1033, 1994; Form PTO-1449, Paper No.

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6, page 3), Anderson, et al (*Clinical Immunology and Immunopathology* **84**: 73-84, 1997), McLaughlin, et al (*Oncology* **12**: 1763-1769, 1998), the Internet edition of the Bioprobe BV Catalog of Mouse Hybridomas (Bandung, Indonesia), Gallizia, et al (*Protein Expression and Purification* **14**: 192-196, 1998; Form PTO-1449, Paper No. 6, page 3), and Pahler, et al (*Journal of Biological Chemistry* **262**: 13933-13937, 1987), Aragarana, et al (*Nucleic Acids Research* **14**: 1871-1882, 1986; Form PTO-1449, Paper No. 6, page 1), Ohno, et al (*DNA and Cell Biology* **15**: 401-406, 1996; Form PTO-1449, Paper No. 6, page 5), and Goshorn, et al (*Cancer Research* **53**: 2123-2127, 1993; Form PTO-1449, Paper No. 6, page 3) for the reasons stated in the Office actions mailed June 22, 2001 (Paper No. 8) and May 21, 2002 (Paper No. 16).

Applicants have traversed the rejection of the claims under 35 USC § 103(a), arguing the prior art does not teach or suggest the disclosed “genomic streptavidin fusion proteins”, which are distinguishable from “core streptavidin fusion proteins”.

Applicants’ arguments have been carefully considered but not found persuasive, since the claims define “genomic streptavidin fusion proteins” and the limitations of the claims are met by the prior art, or would have been obvious to one of ordinary skill in the art at the time the invention was made given the teachings of the prior art.

Furthermore, in response to Applicants’ apparent argument that the Examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See In re Gorman, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Finally, the Examiner disagrees with Applicants’ assertion that the teachings of the prior art “teach away” from the claimed invention. To the contrary, the teachings of the prior art would have provided the artisan of ordinary skill the necessary motivation to make and use the claimed invention. Again, as noted in the previous Office action, the fact that Applicants have recognized another advantage, which would flow naturally from following the suggestion of the prior art, cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

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Therefore, the rejection of claims 18-22, 24-39, and 65 under 35 U.S.C. 103(a) as being unpatentable over Dubel, et al, as evidenced by Kipriyanov, et al, in view of Desplancq, et al, Anderson, et al, McLaughlin, et al, the Internet edition of the Bioprobe BV Catalog of Mouse Hybridomas, Gallizia, et al, Pahler, et al, Aragarana, et al, Ohno, et al, and Goshorn, et al for the reasons stated in the previous Office actions mailed June 22, 2001 (Paper No. 8) and May 21, 2002 (Paper No. 16) is maintained.

***New Grounds of Claim Rejections***

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 34 contains the trademark Primatized™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a recombinant antibody having particular characteristics and, accordingly, the identification/description is indefinite.

***Double Patenting***

11. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 18-22, 26, 28, and 33-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-26 and 71-80 of co-pending Application No. 10/150,762. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of claims 17-26 and 71-80 of co-pending Application No. 10/150,762 is encompassed by claims 18-22, 26, 28, and 33-39 of this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 18-22, 24-39, and 65 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-42 and 77-81 of co-pending Application No. 10/013,173. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of claims 18-42 and 77-81 of co-pending Application No. 10/013,173 is encompassed by claims 18-22, 24-39, and 65 of this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**C nclusion**

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached at (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
January 8, 2003

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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